



Practitioner's Docket No. 1581/130

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application  
of \_\_\_\_\_

Inventor(s)

for \_\_\_\_\_

Title of invention

\_\_\_\_\_ the specification of which is being transmitted herewith

OR

In re application of: Fotinos, Spiros

Application No.: 10/084,264

Group No.: 1619

Filed: February 26, 2002

Examiner: Not yet Assigned

For: Devices and Methods for the Release of Volatile Substances and Applications Thereof

Commissioner for Patents  
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***  
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*Express Mail* certification is optional.)

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10\*

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Date: September 16, 2002

Robert M. Asher

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).  
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e. requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

**NOTE:** "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

**NOTE:** The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

### **List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☒ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ EPO Search Report
  - 7B. ☒ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

**NOTE:** "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

**Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

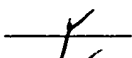
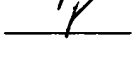
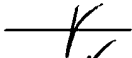
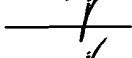
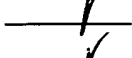
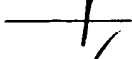

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

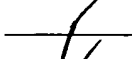
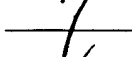
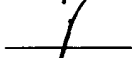
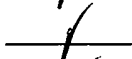
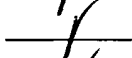
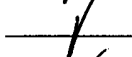
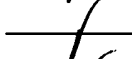
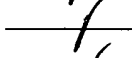
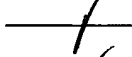
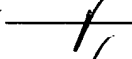
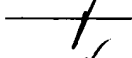
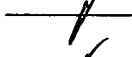
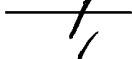
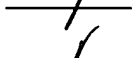


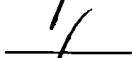

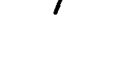
Applicants: Fotinos, Spiros                      Attorney Docket: 1581/130  
 Serial No: 10/084,264                      Art Group Unit: 1619  
 Date Filed: February 27, 2002                      Examiner Name: Not yet assigned  
 Invention: Devices and Methods for the Release of Volatile Substances and  
 Applications Thereof

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE STATEMENT****United States Patents**

Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
/	AA	1,122,796	08/07/68	Girardiere	A5 B(3, 4, 31)
/	AB	4,675,009	06/23/87	Hymes et al.	604/304
/	AC	4,681,635	07/21/87	Stiefel et al.	106/178
/	AD	4,729,190	03/08/88	Lee	47/57.6
/	AE	5,071,704	10/10/91	Fischel-Ghodsian	428/354
/	AF	5,094,237	03/10/92	Peters	128/368
/	AG	5,181,510	01/26/93	Peters	128/368
/	AH	5,234,140	08/10/93	Demarest et al.	222/394
/	AI	5,456,745	10/10/95	Roreger et al.	106/128
/	AJ	5,462,746	10/31/95	Wolter et al.	424/449
/	AK	5,536,263	07/16/96	Rolf et al.	603/307
/	AL	5,616,333	04/01/97	Hayes	424/402
/	AM	5,618,515	04/08/97	Singh et al.	424/45
/	AN	5,620,695	04/15/97	Elliott	424/405
/	AO	5,656,282	08/12/97	Cook et al.	424/409
/	AP	5,716,928	02/10/98	Benet et al.	514/11
/	AQ	5,741,510	04/21/98	Rolf et al.	424/448

	AR	5,746,354	05/05/98	Perkins	222/132
	AS	5,888,984	03/30/99	Brown	514/54
	AT	5,902,601	05/11/99	Horstmann	424/448
	AU	5,928,661	07/27/99	Fujita et al.	424/402
	AV	6,096,333	08/01/00	Rolf et al.	424/443
	AW	6,096,334	08/01/00	Rolf et al.	424/443
	AX	6,335,388 B1	01/01/02	Fotinos	524/20

### International Patents

Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AY	DE 2,011,235	10.03.70	Heimbach	30 h, 2/03
	AZ	DE 2,147,246	27.07.72	Sfitzer et al.	C09K 3/00//B 29 d 27/00
	BA	WO 91/15117	17.10.91	Potter	A01N 25/30
	BB	WO 92/06701	30.04.92	Huffstutler	A61K 35/78
	BC	EP 0 518 697 A2	12.06.92	Song et al.	A61K 9/70
	BD	EP 0 518 697 A3	12.06.92	Song et al.	A61K 9/70
	BE	GB 2,260,494 A	21.04.93	Sweeney	A61L 9/01
	BF	EP 0 669 802 B1	10.11.93	Modanesi et al.	A01N 25/28
	BG	WO 94/10842	26.05.94	Modanesi et al.	A01N 25/28
	BH	EP 0 647 913 A2	07.10.94	Hofmann	G06F 19/00
	BI	EP 0 750 905 A2	25.06.96	Kamiya et al.	A61K 7/50
	BJ	WO 96/21462	18.07.96	Postaire et al.	A61K 38/44
	BK	EP 0 761 240 A1	04.09.96	Soeda et al.	A61L 9/04
	BL	WO 97/01348	16.01.97	Nitsas	A61K 35/78
	BM	WO 98/17262	30.04.98	Le Gall	A61K 9/70
	BN	WO 99/17738	15.04.99	Fotinos	A61K 9/60
	BO	WO 99/65430	23.12.99	Cronk	A61F 5/08
	BP	WO 00/16752	30.03.00	Fotinos	A61K 9/70
	BQ	WO 00/33812	15.06.00	Miranda et al.	A61K 9/00

### Other Documents

Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
<u>f</u>	BR	Davis, Patricia	"Aromatherapy An A-Z", Aromatherapy for the Better, pages 348-351, 1988.
<u>f</u>	BS	Santus et al.	"Transdermal enhancer patent literature", Journal of Controlled Release, Vol. 25, pages 1-20, May 27, 1993.
<u>f</u>	BT	Sugibayashi et al.	"Polymers for transdermal drug delivery systems", Journal of Controlled Release, Vol. 29, pages 177-185, February 1994.
<u>f</u>	BU	Thacharodi et al.	"Development and <i>in vitro</i> evaluation of chitosan-based transdermal drug delivery systems for the controlled delivery of propranolol hydrochloride", Bimaterials, Vol. 16, No. 2, pages 145-148, 1995.
<u>f</u>	BV	PCT/ISA/210	International Search Report, Int'l Appl. No. PCT/US99/21580, International filing date 17.09.99, 8 pages.
<u>f</u>	BW	PCT/ISA/210	International Search Report, Int'l Appl. No. PCT/US02/05768, International filing date 27.02.02, 4 pages.

Examiner Signature: 

Date Considered:  10/16/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

01581/00130 216429.1

## Section 6. Copies of Listed Information Items Accompanying This Statement

*NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."*

*NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

☐ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

## **Section 7. Concise Explanation of Non-English Language List Information Items**

**NOTE:** *"A concise explanation of the relevance, as it is presently understood by the individual designated in section 1.56(c) most knowledgeable about the content of the information of each patent, publication, or other information listed that is not in the English language shall be included in any information disclosure statement filed under section 1.97. The concise explanation may be either separate from the specification or incorporated therein." 37 C.F.R. section 1.98(a)(3).*

**NOTE:** *"[T]he explanation required is limited to the relevance as understood by the individual designated in section 1.56(c) most knowledgeable about the content of the information at the time the information is submitted to the Office." Notice of January 9, 1992, 1135 O.G. 13-25 at 14.*

**NOTE:** *"Where the information listed is not in the English language, but was cited in a search report by a foreign patent officer, the requirement for a concise explanation of relevance is satisfied by submitting an English language version of the search report." Notice of January 9, 1992, 1135 O.G. 13-25. at 14.*

**NOTE:** *"The concise explanation requirement for non-English language information may be met by submission of an English language version of the search report indicating the degree of relevance found by the foreign office." Notice of January 9, 1992, 1135 O.G. 13-25, at 20.*

**WARNING:** *"The requirement in section 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application." Notice of January 9, 1992, 1135 O.G. 13-25 at 20 (emphasis added).*



**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this certification is

*(check each applicable item)*

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

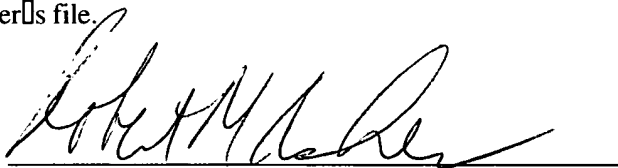
\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

- ☐ supplied by the inventor(s).  
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).  
☒ in the practitioner's file.



\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**

Reg. No.: 30,445

Robert M. Asher

*(type or print name of practitioner)*

Tel. No.: (617) 443-9292

Customer No.: 002101

Bromberg & Sunstein LLP  
125 Summer Street  
Boston, MA 02110-1618